Updated 7/22/2022

IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

STUDY MANAGER STEP-BY-STEP GUIDE

The **IREx Study Manager** is someone from the lead study team or coordinating center who uses IREx to oversee participating site readiness for single IRB (sIRB) review. For more detailed information on how to use IREx, check out the Study Manager User Manual on the IREx Resources page here.

STEP 1 — SUBMIT THE LEAD SITE TO THE SIRB

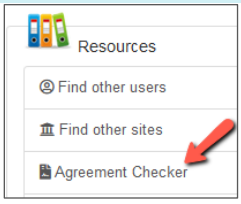
- ❑ Discuss the submission process with the sIRB (e.g., What is needed for the lead site; How are participating sites submitted to the IRB for review?)
- ❑ Ask the sIRB if they want to use the IREx Reliance Instructions template to communicate next steps to sites.

STEP 2 — THE STUDY IS CREATED IN IREX [COMPLETED BY THE SIRB]

You will receive access to IREx via an email notification after the study is created by the sIRB.

STEP 3 — WORK WITH SITES WHO HAVE NOT COMPLETED ALL REQUIRED AGREEMENTS (IF APPLICABLE)

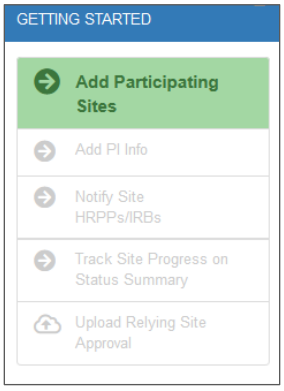
- ❑ Use the **Agreement Checker** tool on the IREx home page to check the agreement status for your sites.
- ❑ In the Agreement Checker, set the sIRB field to the sIRB institution, then enter participating sites' names or FWA #s to build a list (see image below). The list can be downloaded as a CSV file.



Site Name	FWA	SMART 1	SMART 2	IREx	Indemnification
Abington Neurological Associates, Ltd.	#00021171	✓	✗	✗	✗
BayCare Health System	#FWA00006065	✓	✗	✓	✗
Duke University Health Systems, Inc.	#00009025	✓	✗	✓	✓ VUMC LOI

- ❑ If any sites have incomplete agreements or have not joined IREx, request the site investigator work with their local HRPP to complete the missing agreements. Note: The IREx Admin Team can provide template language describing the importance of completing any missing agreements, if needed.
- ❑ Sites that have completed all agreements do not have any action items until the lead site is approved.

STEP 4 — ADD SITES TO THE STUDY IN IREX



- ❑ Use the GETTING STARTED checklist to guide your steps in IREx. The first step is to **Add Participating Sites** to the study so you can track their agreement status.
- ❑ Add sites using the institution name (avoid abbreviations) or Federalwide Assurance # (FWA). Note: Once you start entering the site name or FWA, you can select the site from the drop-down menu. You can also add sites that do not appear in the search.
- ❑ A PI name and email address are required before the site can be notified of the study, but you can list the site name without the PI and retun later to enter it.

Tip: We also recommend including a site coordinator name and email, if known.

THESE STEPS OCCUR AFTER LEAD SITE APPROVAL

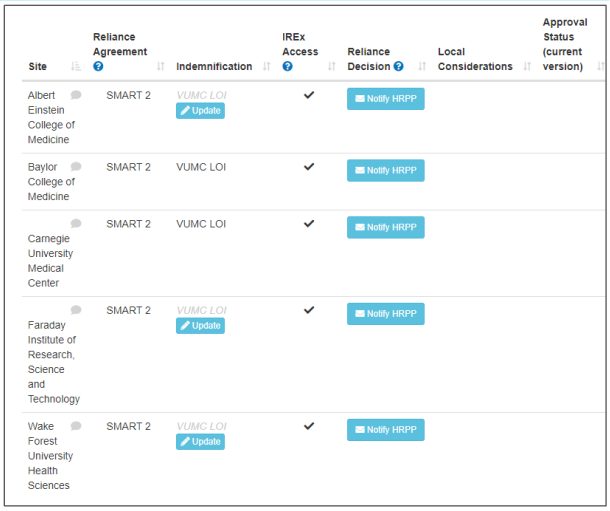
STEP 5a — EMAIL APPROVED STUDY MATERIALS TO STUDY TEAMS (OUTSIDE OF IREX)

- ❑ Sites need the approved study materials to submit to their local HRPP, which is usually required before their HRPP can complete documentation in IREx and grant their study teams access to IREx.
- ❑ Include the approved protocol and consent templates; lead site IRB approval letter; reliance instructions; contracts; and other regulatory documents. You can also share this 5-minute IREx video tutorial.

STEP 5b — NOTIFY SITES OF THE STUDY IN IREX

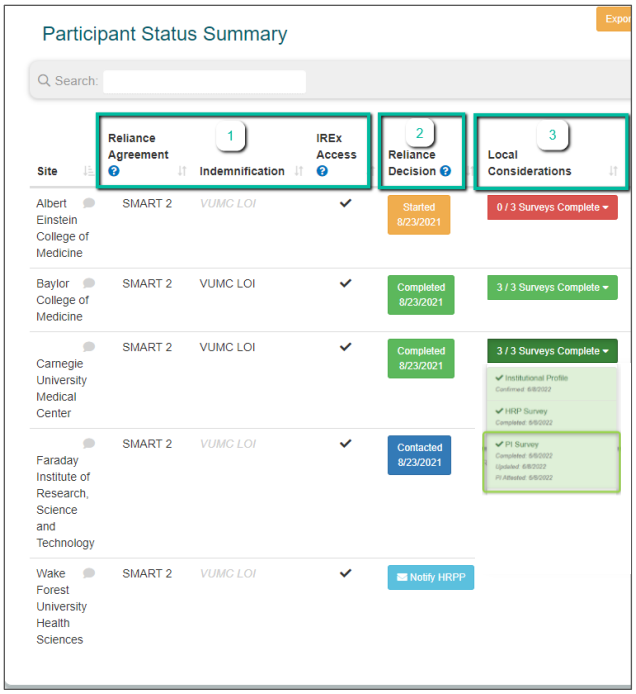
After the lead site is approved and the approved study materials are sent to study teams:

- ❑ From the Status Summary tab, click **Notify HRPP** to alert site HRPPs of their access to the study in IREx. This sends an email to the HRPP and study team and prompts them to connect around their local reliance process. You, the local site PI, and coordinator (if provided) are copied on the email.
- ❑ You can notify sites at different times, depending on when they are being onboarded to the study.
  Tip: Only sites with IREx access can be notified. Non-IREx site's HRPP/IRB director or manager can join here.



STEP 6 — TRACK SITE READINESS FOR SIRB REVIEW USING THE STATUS SUMMARY TAB

1. Has the site signed all the required agreements?
   - SMART IRB Agreement, IAA or MOU
   - Indemnification (if applicable)
   - IREx Access (HRPP can join here)
2. Has the site's HRPP indicated reliance?
   - **Add PI Info** = study manager must add PI email & name before site can be notified and rely
   - **Notify HRPP** = site has not been contacted about the study and cannot access it in IREx
   - **Contacted** = date study notification was sent (click to send reminder, as needed)
   - **Started** = date HRPP registered and accessed study
   - **Completed** = date HRPP indicated reliance
   - **Incomplete** = incomplete agreements
3. Are local considerations complete?
   - **Institutional Profile**: Completed by the HRPP and includes institution-level information.
   - **HRP Survey:** Completed by the HRPP and includes applicable local requirements for this study.
   - **PI Survey:** Completed by the PI or coordinator; includes information about the conduct of the study and an upload of the locally reviewed consent document(s). The PI must attest to the survey, as well as any edits made by a coordinator or the HRPP.

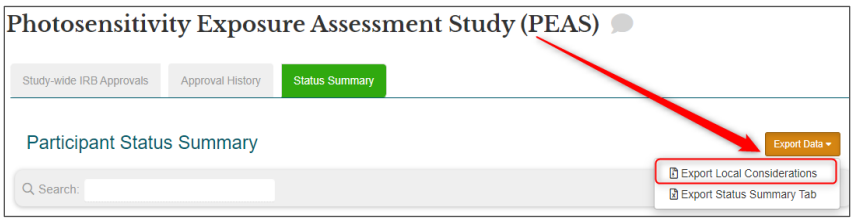


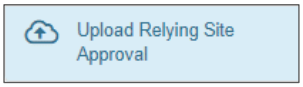
STEP 7 — SITE TRACKING AND FOLLOW UP REGARDING OUTSTANDING ACTION ITEMS

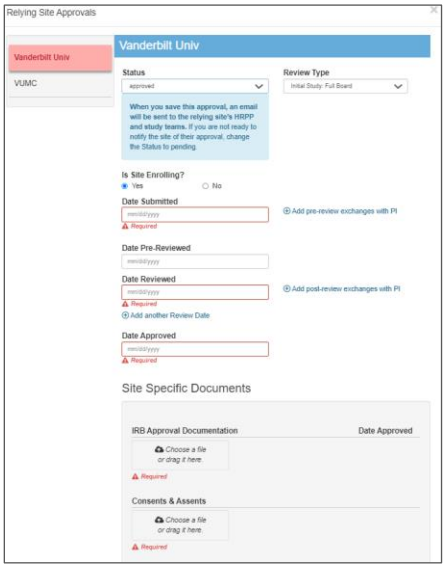
Use the Status Summary tab to guide your follow-up with site study teams.

- ❑ View who has access for each site in the Participating Personnel dialog at the top of the study page.
- ❑ **If sites request that their IREx invitation be re-sent,** you can press **Contacted** to re-send the notification.
- ❑ **If steps are incomplete,** ensure the study team has submitted to their local HRPP. If so, ask the study team to follow up with their IREx HRPP Liaison (found here) regarding steps in IREx or additional requirements.
- ❑ **Incomplete PI Survey: If PI or Coordinator has IREx access,** send a reminder to complete the PI Survey.
- ❑ Edit the list of participating sites using the **Manage Project** button **> Edit Participating Sites** or the **Getting Started** checklist **Add Participating Sites** button

	Tip: Ensure newly added sites have reliance instructions, the approved study materials, the Part 2 consent template (if applicable) and an introduction to using a Single IRB.
STEP 8	**PRE-SCREEN AND EXPORT LOCAL CONSIDERATIONS** (IF APPLICABLE) You will receive an email from IREx when a site completes local considerations. ❑ Pre-screen the surveys for completion by clicking on each local consideration survey on the Status Summary tab. ❑ Ensure consent forms are uploaded to the PI Survey, if applicable, and that they are correct. ❑ **If changes or clarifications are needed, the PI and Coordinator (or HRPP Liaison) at the site can edit the PI Survey. Only the HRPP can edit the HRP survey.** ❑ Once the pre-screening is complete, the site is ready to be submitted for sIRB review. ❑ When a site is ready to be submitted to the sIRB, from the Status Summary tab, click the **Export Data** button and select **Export Local Considerations** to download a zip file of sites' completed local considerations. Select the site(s) you need and save their files. ❑ Submit the site's files to the sIRB for review.
STEP 9	**UPLOAD INITIAL SIRB APPROVALS FOR PARTICIPATING SITES** To upload a site approval, click the **Upload Relying Site Approval** step on your GETTING STARTED checklist or the site's 'Not Approved' status on the Status Summary tab: ❑ Select the **site name** from the list of sites on the left panel; ❑ Change the Status to **approved**; ❑ Indicate the **Review Type** (Full Board or Expedited); ❑ **Is Site Enrolling?** Defaults to **Yes**, change to **No** if the site will not be enrolling participants and does not need a consent form. ❑ Enter the **Date Submitted, Reviewed,** and **Approved**; and ❑ Upload the site's **IRB Approval Documentation, Consents & Assents** (or waive), and other site-specific IRB approved documents. ❑ Press **Save**. **The site HRPP and study team are notified by email when new approvals are saved, and you are cc'd.**





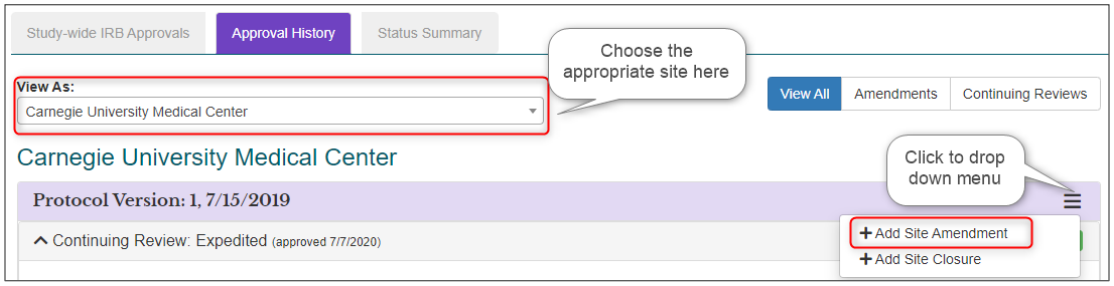


STEP 10

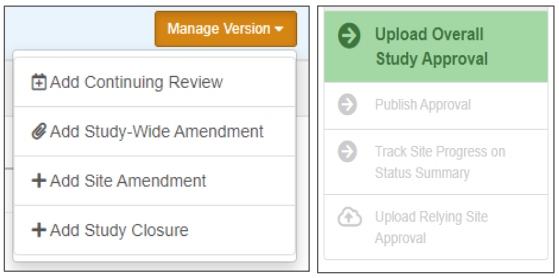
UPLOAD OTHER IRB DETERMINATIONS FOR THE STUDY AND PARTICIPATING SITES

Study Managers can upload additional sIRB approvals. Please confirm the sIRB prefers you upload these:

1. Site Amendments (Quick Guide): Upload site changes (e.g., PI change) from the **Approval History** tab. Select the site under **View As**, click the menu, and click **+Add Site Amendment**.

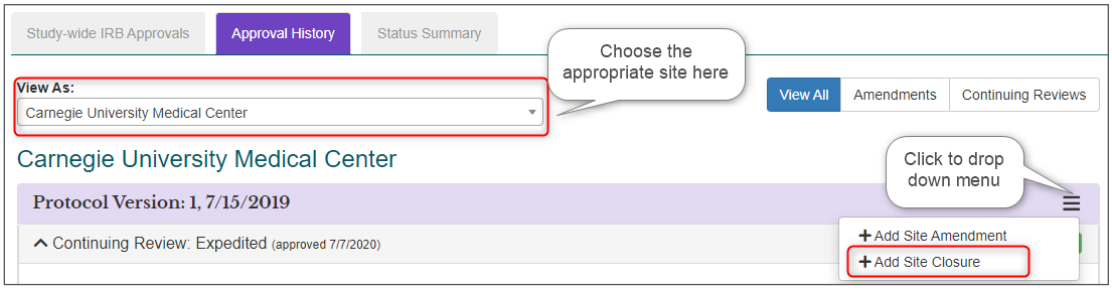


2. Continuing Reviews (Quick Guide) & Study-wide Amendments (Quick Guide): Each has **3 steps**:



   a. **Add the approval:** From the **Manage Version** menu, select the approval type and complete the information in the dialog.
   b. **Upload sIRB approval for lead site/ overall study:** From your GETTING STARTED checklist, click **Upload Overall Study Approval**, after setting the status to approved, the required fields will be highlighted. Once completed, publish the approval for the lead site. (Sites are NOT notified until the next step is completed.)
   c. **Upload sIRB approvals for Relying Sites:** From your GETTING STARTED checklist, click **Upload Relying Site Approval.** After selecting a site and changing their status to approved, the lead site's review dates will auto-fill. Be sure to delete any files that are no longer in use or applicable and upload updated / new documents for the site.

3. **Site Closure:** IREx can be used to document and communicate site closures. Closing a site ensures that only active sites retain access to ongoing studies. See the Site Closure Quick Guide for more information.
   a. Upload a site closure from the **Approval History** tab. Select the site under **View As**, click the menu, and click **+Add Site Closure**.
   b. Once the site is closed, a notification is sent to the closed site's liaisons and study contacts. They retain access for 30 days.



4. **Study Closure:** IREx can be used to document and communicate study closures. Closing a study ensures all sites are aware that the study ended but retains a record of all reliances and a history of sIRB site approvals. See the Study Closure Quick Guide for more information.
   a. Initiate a study closure by clicking **Add Study Closure** on the **Manage Version** menu.
   b. Once the closure is published, a notification is sent to each site (individually) that the study was closed.